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| 10/825,367 | 04/16/2004 | Martin Svchla | COCH-0051-UT1 | 8100 |
| 30678 7590 09/12/2007 CONNOLLY BOVE LODGE & HUTZ LLP 1875 EYE STREET, N.W. SUITE 1100 WASHINGTON, DC 20036 | | | EXAMINER SONNETT, KATHLEEN C | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/825,367 | Applicant(s) SVEHLA ET AL. | |
| | Examiner Kathleen Sonnett | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-76 is/are pending in the application.
- 4a) Of the above claim(s) 38-72 and 74-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-37 and 73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species I in the reply filed on 6/14/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Response to Arguments

2. Applicant's arguments with respect to new claims 20-37 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 20, 21, 23, 24, 35, 37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Cichon (U.S. 1,657,497). Cichon discloses a manually adjustable forceps tool capable of controlling an implantable electrode assembly of a stimulating medical device comprising a first flexible arm (7) comprising contiguous first and second elongate regions having proximal and distal ends, the second region (8) having a concave shaped region (11) near said distal end of the second region and a second flexible arm comprising first and second contiguous elongate regions with proximal and distal ends, the second region of the second arm having a tip region wherein the proximal end of the first region of the first arm is pivotally fixed to the proximal end of the first region of the second arm, and wherein application of a force to the

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first and second arms causes the tip region to be in proximity to the concave region to retain the electrode assembly in a space defined by the concave region and the tip region.

5. Regarding claim 21, the concave region (11) can be considered to have a substantially C-shaped cross section since the concave region is a semicircle.

6. Regarding claims 23 and 24, when an electrode assembly is retained between the concave region and the tip region, the concave region limits lateral movement of the electrode assembly while allowing longitudinal movement. This would occur if, for example, a cylindrical electrode were placed within the space such that the longitudinal axis of the concave region was the same as that of the electrode.

7. Regarding claim 35, when the arms are compressed the distal ends of the second regions move toward each other.

8. Regarding claim 37, the forceps are capable of holding any of the electrode arrays listed in claim 37.

9. **Claims 20-24, 27, 35, 37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Blomberg (U.S. 3,738,366). Blomberg discloses a manually adjustable forceps tool capable of controlling an implantable electrode assembly of a stimulating medical device comprising a first flexible arm (17) comprising contiguous first and second elongate regions having proximal and distal ends, the second region (1) having a concave shaped region (20) near said distal end of the second region and a second flexible arm (18) comprising first and second contiguous elongate regions with proximal and distal ends, the second region of the second arm having a tip region (21) wherein the proximal end of the first region of the first arm is pivotally fixed to the proximal end of the first region of the second arm, and wherein application of a force to the first and second arms causes the tip region to be in proximity to the

concave region to retain the electrode assembly in a space defined by the concave region and the tip region.

10. Regarding claims 21 and 22, the concave region comprises a region having a substantially C-shaped cross-section. This can be considered a half-tube shaped section as well (see fig. 6).

11. Regarding claims 23 and 24, when an electrode assembly is retained between the concave region and the tip region, the concave region limits lateral movement of the electrode assembly while allowing longitudinal movement depending on how the electrode is held within the assembly.

12. Regarding claim 27, a line through the center of the space defined by the concave region is substantially aligned with the longitudinal axis of the second region of the first arm (fig. 1).

13. Regarding claim 35, when the arms are compressed the distal ends of the second regions move toward each other.

14. Regarding claim 37, the forceps are capable of holding any of the electrode arrays listed in claim 37.

15. **Claims 20, 21, 32, 33, 37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Baschenis (U.S. 6,352,293). Baschenis discloses a manually adjustable forceps tool capable of controlling an implantable electrode assembly of a stimulating medical device comprising a first flexible arm (16) comprising contiguous first and second elongate regions having proximal and distal ends, the second region having a concave shaped region (26) near said distal end of the second region and a second flexible arm (14) comprising first and second contiguous elongate regions with proximal and distal ends, the second region of the second arm having a tip region (28) wherein the proximal end of the first region of the first arm is pivotally

fixed to the proximal end of the first region of the second arm, and wherein application of a force to the first and second arms causes the tip region to be in proximity to the concave region to retain the electrode assembly in a space defined by the concave region and the tip region. This force is provided by the material, which has sufficient resiliency to move the second regions toward each other.

16. Regarding claim 21, a cross section of the very middle of the concave shaped region (26) will have a C-shaped cross section.

17. Regarding claims 32 and 33, the tip region extends the length of the second region (in this case the second region is being considered to include only the distal most region of the second arm that corresponds to the concave shaped region of the first arm and the first region makes up the remainder of the first arm). The tip region has an approximately constant cross section and will be substantially rectangular.

18. **Claims 20-24, 27, 32, 37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Baccala et al. (U.S. 4,785,810). Baccala discloses a manually adjustable forceps tool capable of controlling an implantable electrode assembly of a stimulating medical device comprising a first flexible arm (region distal of pin (50)) comprising contiguous first and second elongate regions (second region starting at bend) having proximal and distal ends, the second region having a concave shaped region (16) near said distal end of the second region and a second flexible arm (distal of pin (50)) comprising first and second contiguous elongate regions with proximal and distal ends, the second region of the second arm having a tip region (28) wherein the proximal end of the first region of the first arm is pivotally fixed to the proximal end of the first region of the second arm, and wherein application of a force to the first and second arms causes the tip region to be in proximity to the concave region to retain the electrode assembly in a space defined by the concave region and the tip region.

19. Regarding claims 21 and 22, a cross section of the concave shaped region (26) will have a C-shaped cross section and substantially half-tube shaped.

20. Regarding claims 32, the tip region extends the length of the second region (entire portion after bend in arm) and has an approximately constant cross-section.

21. **Claims 20, 21, 23-25, 35-37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Ruggles (U.S. 1,033,942). Ruggles discloses a manually adjustable forceps tool capable of controlling an implantable electrode assembly of a stimulating medical device comprising a first flexible arm comprising contiguous first and second elongate regions having proximal and distal ends, the second region having a concave shaped region near said distal end of the second region and a second flexible arm comprising first and second contiguous elongate regions with proximal and distal ends, the second region of the second arm having a tip region wherein the proximal end of the first region of the first arm is pivotally fixed to the proximal end of the first region of the second arm, and wherein application of a force to the first and second arms causes the tip region to be in proximity to the concave region to retain the electrode assembly in a space defined by the concave region and the tip region (see fig. 3).

22. Regarding claims 23 and 24, when an electrode assembly is retained between the concave region and the tip region, the concave region limits lateral movement of the electrode assembly while allowing longitudinal movement depending on how the electrode is held within the assembly.

23. Regarding claim 25, the second regions are positioned at an angle of approximately 0 degrees from the first regions.

24. Regarding claim 35, when the arms are compressed the distal ends of the second regions move toward each other.

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25. Regarding claim 36, Ruggles discloses a post (alpha; fig. 1, 3) on one of the arms that prevents the tip region from contacting the concave region.

26. Regarding claim 37, the forceps are capable of holding any of the electrode arrays listed in claim 37.

27. **Claims 20, 29, 32, 34, 37, and 73** are rejected under 35 U.S.C. 102(b) as being anticipated by Weinrib (U.S. 4,793,349). Weinrib discloses a manually adjustable forceps tool capable of controlling an implantable electrode assembly of a stimulating medical device comprising a first flexible arm comprising contiguous first and second elongate regions having proximal and distal ends, the second region having a concave shaped region (curved tip 40) near said distal end of the second region and a second flexible arm comprising first and second contiguous elongate regions with proximal and distal ends, the second region of the second arm having a tip region wherein the proximal end of the first region of the first arm is pivotally fixed to the proximal end of the first region of the second arm, and wherein application of a force to the first and second arms causes the tip region to be in proximity to the concave region to retain the electrode assembly in a space defined by the concave region and the tip region (see fig. 1).

28. Regarding claims 29, 32 and 34, the tip region extends the length of the second region of the second arm and comprises an approximately constant cross-section. The tip region is approximately half-circular shaped in cross-sectional (see fig. 5a) wherein the flat surface is proximate to the concave region (curved tip 40) when the tip is in proximity to the concave region.

Claim Rejections - 35 USC § 103

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. **Claims 25 and 26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cichon in view of Hanna (U.S. 4,873,979). Cichon discloses the invention substantially as stated above including that the second regions of the first and second arms are each positioned at a small angle relative to their first regions (see fig. 3). Cichon is silent on the degree of the angle.

31. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to change this angle to 18 degrees since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)). That is, the instrument of Cichon is used to grasp small articles and the appropriate bend angle of the tip changes depending on the intended use of the instrument. Smaller bend angles allow access to smaller spaces. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Hanna change the bend angle from 30 degrees to 18 degrees since it would involve only routine skill in the art to find an optimum value.

32. **Claim 28** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruggles in view of Thuerig (U.S. 2,642,871). Ruggles discloses the invention substantially as stated above but fail to disclose aperture in the trough of the concave region.

33. However, Thuerig disclose that it is old and well known in the art to include a hole in the tip of a clasping tool in order to reduce the weight of the instrument (col. 2, ll. 1-3). This may also decrease the cost of the materials used to construct the instrument. Therefore, it would have been obvious to one skilled in the art to modify Ruggles to include an aperture in the trough of the concave region in order to reduce the weight of the device.

34. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinrib in view of Sanders (US 1,704,992). Weinrib discloses the invention substantially but fails to disclose that the width of the flat surface is greater than the width of the space defined by the concave region.

35. However, Sanders discloses that it is old and well known to have a thinner tip region which engages a concave region in a needle holding forcep type instrument. The smaller size allows the tip region to extend deeper into the concave region, thereby imparting a tighter hold on the needle. Therefore, it would have been obvious to one skilled in the art to modify Weinrib in view of Sanders to size the rip region such that its width is less than the width of the concave region in order to change the tightness of the hold on the needle.

36. **Claims 30 and 31** rejected under 35 U.S.C. 103(a) as being unpatentable over Weinrib in view of Clayton (US 791,322). Weinrib discloses the invention substantially but fails to disclose that the width of the flat surface is greater than or less than the width of the space defined by the concave region.

37. However, Clayton discloses forceps type instrument used to hold a needle wherein the tip regions of the jaws are not the same width (see fig. 8). It is known to those skilled in the art to pair jaw members together with different widths in order to change the grip on the device being held by the jaws and it would have been obvious to one skilled in the art to modify Weinrib to include a tip region that is wider or thinner than the space defined by the concave region in order to change the grip on the device being held between the jaws.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 8/21/2007


GLENN K. DAWSON
PRIMARY EXAMINER